HFA-305

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

3015 '02 JUL 10 A9:34

The Weinberg Group, Inc.
Attention: Nicholas M. Fleischer, Ph.D.
1220 Nineteenth St. N.W., Suite 300
Washington, DC 20036-2400

JUL - 3 2002

Docket No. 01P-0283/CP1

Dear Dr. Fleischer:

This is in response to your petition filed on June 26, 2001, and your amendment dated June 26, 2001, requesting permission to file an Abbreviated New Drug Application (ANDA) for the following drug product: Pentoxifylline Extended-release Tablets, 500 mg. The listed drug product to which you refer in your petition is Trental® (Pentoxifylline) Extended-release Tablets, 400 mg, NDA 18-631, held by Aventis Pharmaceuticals, Inc.

This petition was reviewed pursuant to Section 505(j)(2)(C) of the Federal Food, Drug, and Cosmetic Act (Act). Under Section 505(j)(2)(C)(i) of the Act such a petition will be approved unless the Food and Drug Administration (FDA) finds that investigations must be conducted to show the safety and effectiveness of the strength for the proposed drug product which differs from the strength of the listed drug product.

Your request involves a change in strength from that of the listed drug product (i.e., from 400 mg to 500 mg, a new higher strength). The change in strength that you request is the type of change that is authorized under Section 505(j)(2)(C) of the Act. In addition, you request an additional dosing regimen (i.e., one 500 mg Pentoxifylline Extended-release Tablet two times a day with meals). This is a change that is not permitted under Section 505(j)(2)(C) of the Act.

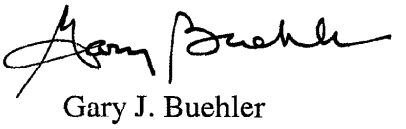
The FDA has determined that your proposed changes in strength and dosage regimen raise questions of safety and effectiveness, and has concluded that clinical trials are required for this specific drug product. FDA has safety concerns regarding possible kidney and/or liver toxicities resulting from increased peak plasma levels from the 500 mg dose. Furthermore, this change in strength and dosing regimen is not supported by the approved labeling for the listed drug. Therefore, FDA is denying the petition under Section 505(j)(2)(C)(i) because investigations are necessary to show the safety and effectiveness of the proposed drug product and because a change in dosage regimen is not petitionable under Section 505(j)(2)(C) of the Act. Please contact the Division of Cardio-Renal Drug Products at (301) 594-5300 if you wish to pursue approval of your product under Section 505(b) of the Act.

01P-0283 PDN 1

If you disagree with our determination concerning the acceptability of your petition as originally submitted, you may seek a reconsideration of the denial following the procedures set forth in 21 CFR 10.33. Requests for reconsideration must be based solely on the information contained in your original petition and must be submitted in accordance with 21 CFR Section 10.20, in the format outlined in Section 10.33 and no later than 30 days after the date of the decision involved. Petitions for reconsideration should be filed with the Dockets Management Branch at the address listed below. If there is additional information, not included as part of your original submission that you would like the FDA to consider, you should submit a new petition including all the necessary information to the Dockets Management Branch.

A copy of this letter denying your petition will be placed on public display in the Dockets Management Branch, Room 1061, Mail Stop HFA-305, 5630 Fishers Lane, Rockville, MD 20852.

Sincerely yours,



Gary J. Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research